

# INTRODUCING THE TEARLAB OSMOLARITY SYSTEM



 **TearLab**™  
Osmolarity System

## ▶ THE FIRST POINT-OF-CARE TEAR TEST TO PROVIDE LABORATORY ACCURATE RESULTS

Dry Eye Disease is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.

Osmolarity is a basic and essential aspect of physiologic homeostasis in body fluids. Small deviations in homeostasis, such as pH, temperature, glucose and oxygen concentrations,

and osmotic pressure activate physiological mechanisms to return that variable to its set point. The body is able to regulate osmolarity of body fluids within very narrow limits through various mechanisms of osmoregulation, such as the compensation and correction of fluid volume and salt concentration. Hyperosmolarity of any body fluid, including tear fluid, indicates a disorder in the body's ability to regulate homeostasis and is a basic indication of a physiological disorder.

▶ **NEW AID IN THE DIAGNOSIS OF DRY EYE DISEASE**

- ▶ The TearLab Osmolarity System is intended to measure the osmolarity of human tears to aid in the diagnosis of Dry Eye Disease in patients suspected of having Dry Eye Disease, in conjunction with other methods of clinical evaluation. TearLab requires less than 50 nL (nanoliters) of tear fluid and displays quantitative osmolarity results in seconds. TearLab is for professional *in vitro* diagnostic use only.
- ▶ Tear osmolarity has been shown to have the highest predictive value for diagnosing Dry Eye Disease of any single test.

PREDICTIVE VALUE	Clinical Test	Positive Predictive Value
	Osmolarity <sup>2</sup>	
Schirmers <sup>1</sup>		31%
Tear Film Breakup Time <sup>1</sup>		25%
Staining <sup>1</sup>		31%
Meniscus Height <sup>1</sup>		33%

- ▶ The TearLab Osmolarity System has demonstrated precision and accuracy consistent with existing laboratory osmometers.

PRECISION <sup>4</sup>	Average Osmolarity (mOsms/L)	Within Run (SD)	Within Run (CV%)
	280		3.8
294		5.5	1.85%
316		4.5	1.41%
345		4.5	1.30%

ACCURACY <sup>4</sup>	No. Sites	N	Regression Line	r <sup>2</sup>
	3		120	y = 0.9402x + 12.512

▶ **OSMOLARITY AND DRY EYE DISEASE**

Dry Eye Disease is a condition of gradual onset and progression, so in early disease, full expression of disease markers may not be evident or may be intermittent. This may lead to misclassification of

some disease subjects as normal; or normal as dry eye. As seen in the graph below, osmolarity correlates well with early, middle, and late-stage disease.

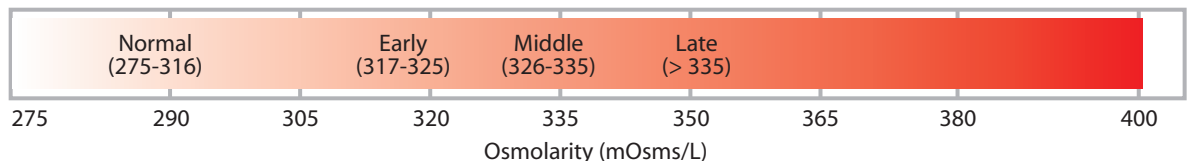


Figure 1. TearLab™ Osmolarity correlates with Dry Eye Disease.<sup>4</sup>

▶ **EXPECTED RESULTS**

Normal: Mean 309.9 mOsms/L ± 11.0

Dry Eye Disease: Mean 324.3 mOsms/L ± 20.1

*Osmolarity may differ from left to right eye, and each eye should be tested and assessed to determine which eye represents the higher osmolarity.*

**FOR MORE INFORMATION, PLEASE CONTACT:**

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FDA 510(k) Cleared (K083184)

References

1. "Definition and Classification of Dry Eye. Report of the Diagnosis and Classification Subcommittee of the Dry Eye Workshop (DEWS)." *The Ocular Surface* 5(2): 75-92, 2007.
2. Tomlinson A., McCann L., Pearce E.I. Comparison of OcuSense and Clifton Nanolitre Osmometers. IOVS ARVO Abstract, 2009. Dept. of Vision Sciences, Glasgow Caledonian University, UK
3. Tomlinson A. et al., "Tear Film Osmolality: Determination of a Referent for Dry Eye Diagnosis," *Investigative Ophthalmology & Visual Science*, October 2006; 47(10) 4309-4315.
4. TearLab Corporation 510K Submission 2009.

One or more of the following patents may apply: U.S. Patents 7,017,394, 7,051,569, 7,111,502, 7,129,717, 7,204,122



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